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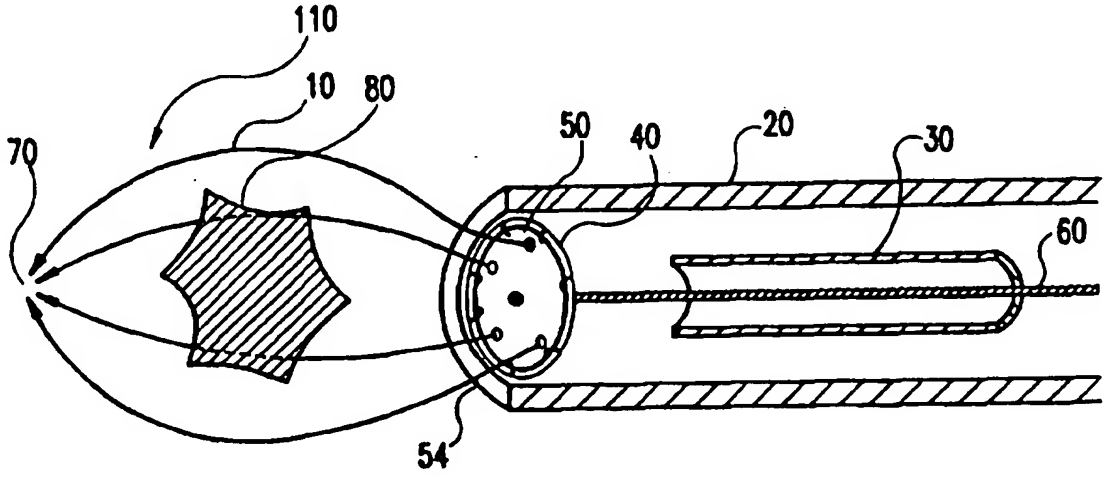
(54) Title: LUMPECTOMY FACILITATING APPARATUS AND METHODS RELATED THERETO



(57) Abstract

An apparatus for marking a predetermined tumor free margin around a tumor mass (80) is provided. The apparatus includes a needle (20) with one or more margin wires (10) located therein. The margin wires (10) are deployed from the needle (20) at a predetermined distance from a tumor mass (80) so as to form a cage (110) around the tumor mass (80). The cage (110) is used during a lumpectomy operation to guide the surgeon in the removal of the tumor mass (80) with an approximately uniform margin of tumor free tissue.

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LUMPECTOMY FACILITATING APPARATUS AND METHODS RELATED THERETO

RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application Serial No. 60/014,976 filed April 8, 1996 and U.S. Provisional Application Serial No. 60/004,715 filed October 3, 1995.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to an apparatus for marking a tumor mass so that a surgeon can locate the tumor mass during a lumpectomy operation, and more particularly to an apparatus which can be used to guide the surgeon during the removal of the tumor mass so that a single fragment of tissue with a tumor mass centrally located therein can be removed.

Description of Related Art

Devices are known which can be used to mark the location of a tumor for a lumpectomy operation. However, these devices merely indicate the approximate general location of a tumor and do not define the boundaries of a tumor or mark excisional free tissue margins. As a

result, suboptimal or inadequate lumpectomy specimens are often obtained.

In particular, since the devices merely indicate the location of the tumor mass and since the boundaries of the tumor mass are often difficult to determine, it is common for the tumor mass to be located at a margin of the specimen which is removed. As such, cancerous tissue is often left within the breast after the lumpectomy specimen has been removed. When the tumor mass is at or close to one margin of the specimen, the surgeon must then remove a second piece of tissue in an attempt to remove any remaining cancerous tissue. However, there is no way to ensure that the second piece of tissue is taken from the correct location or that all of the cancerous tissue has been removed. In addition, even if the operating surgeon is confident that the tumor mass is completely removed, this fact cannot be verified by the examining pathologist since the lumpectomy specimen may be in fragments.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide an apparatus which facilitates the removal of lumpectomy specimens by defining a circumferential area around a tumor mass which is a predetermined distance from the tumor mass.

It is another object of the invention to provide an apparatus comprising a housing needle which includes one or more margin wires which can be deployed to form a cage around a tumor mass so as to provide a

guide for the removal of the tumor with an approximately uniform margin of tumor-free tissue.

It is a further object of the invention to provide a method of defining an approximately uniform tumor-free area around a tumor mass.

It is also an object of the present invention to provide a method of removing a tumor mass with a predetermined tumor free margin around the tumor mass.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a cross-sectional view of an apparatus in accordance with the present invention with undeployed margin wires;

Figure 2 is a cross-sectional view of a first embodiment of the apparatus of Figure 1 with the margin wires deployed;

Figure 3 is a cross-sectional view of a housing needle with the margin wires positioned within the wall of the housing needle;

Figure 4 is a perspective view of a second embodiment of the present invention with the margin wires deployed;

Figure 5 illustrates a curved segment through which the margin wires are deployed in accordance with a second embodiment of the invention;

Figure 6A is a side view of a deployed cage; and

Figure 6B is a cross-sectional view of the housing needle after the deployment of the margin wires and decoupling of the housing needle from the wire cage.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

The present invention generally provides an apparatus which includes one or more margin wires housed within a needle. The wires are deployed to form a cage a predetermined distance from and around a tumor mass so as to define a tumor free area around the tumor mass. During surgery, e.g., a lumpectomy operation, the surgeon uses the cage as a guide so that the complete tumor mass surrounded by an approximately uniform tumor free margin of tissue can be removed.

Additionally, a method of defining an area around a tumor mass and a method of removing a tumor mass with an approximately uniform predetermined tumor free margin of tissue are provided.

In general, it has been found that a proper lumpectomy specimen removed at surgery should, in most instances, be a roughly spherically shaped single fragment of tissue which contains the tumor mass centrally located within the tissue fragment with, preferably, approximately 1 cm or more of surrounding tumor-free tissue.

By using the apparatus or methods of the present invention, a proper lumpectomy specimen can be marked and/or removed.

In the practice of the present invention, in order to assure that a tumor free margin is present in all directions from a tumor mass, a housing needle is inserted into a breast so that the end of the needle is positioned approximately 0.7 to 1.3 cm, and preferably, approximately 1 cm, from the tumor mass. The end of the needle can be positioned on one side of the tumor or can be inserted through the tumor, depending on the configuration of and method of deploying the wires. The wires are then deployed from the housing needle through the tissue in a manner so as to form an arc or circle around the tumor mass and thereby define an tumor free area around the tumor mass. The margin wire(s) can partially or fully encompass the tumor mass.

Figure 1 is intended to provide a non-limiting example of an apparatus according to the invention. Figure 1 shows a housing needle 20 which is inserted into the patient's breast. The needle 20 contains margin wires 10 which are attached to one side of a plunger plate 40. A plunger plate advancing rod 30 is attached to a second side of the plunger plate 40 opposite to the margin wires 10. The advancing rod 30 is used to move the plunger plate 40 and thereby move the margin wires 10.

A hub plate 50 is located at the tip of the needle 54 which is inserted into the patient. The hub plate 50 can include channels 52 to guide the margin wires 10 out of the needle 20. The channels 52 can be

straight or can be curved, as will be discussed *infra*. The plunger plate 40 can include a clasping device 42 to lock the plunger plate to the hub plate 50 once the plunger plate has been completely deployed.

As shown in Figure 3, it is also possible for the margin wires 10 to be placed within the wall 100 of a housing needle 20 and then deployed. It is contemplated that other methods for housing the wires within the needle and for deploying the margin wires 10 can be used.

Referring now to Figure 2, the embodiment of Figure 1 is shown with the margin wires 10 after deployment. In this embodiment, the end of the needle 54 is positioned to one side of the tumor mass 80 and the wires 10 move forward in an arc-like manner so as to form a cage or basket 110 around the tumor mass 80.

In the operation of the first embodiment, the advancing rod 30 within the needle 20 drives the margin wires 10 through the channels 52 in the hub plate 50 which is located at the tip of the needle 54. The margin wires 10 have memory characteristics which are activated by any of the known methods, such as stress or thermal activation. Wires with memory characteristics are known in the art and include, for example, arch wires, such as NITINOL® wire (3M Unitek Corporation). The memory characteristics cause the wires to follow a semicircular path through the tissue surrounding the tumor. In general, a wire with memory characteristics indicates that a wire can be maintained in a predetermined orientation until the wire is activated. Upon activation, the wire "remembers" a prior orientation. One example, is a wire which has been bent into a

particular shape and then is straightened. The straight wire can then be stored and later activated when the bent wire is desired.

After deployment, the wires meet at a coterminus 70, thereby forming a cage or a basket 110 around the tumor mass 80 at a predetermined distance away from the tumor mass. The cage 110 can partially or fully encompass the tumor mass 80. It is preferred that the end of the needle is positioned approximately 0.7 to 1.3 cm, and preferably, approximately 1 cm, away from the edges of a tumor mass. The placement of the needle at this distance and the use of wire with memory characteristics or the deployment of wire through a curved channel or segment will produce a cage which is approximately 0.7 to 1.3 cm away from the tumor at all positions.

It is preferred that four to eight margin wires 10 are used to form the cage or basket 110 around the tumor mass 80, however, other numbers of wires can be used. The wires can be coded, such as with color, in order to orient the removed lumpectomy specimen with respect to the margin direction (i.e. anterior, posterior, superior, inferior, right and left). It is also preferred that the margin wires be tempered or hardened so that the wires can only be cut with special cutters, thereby preventing inadvertent fragmentation of the wires by surgical scissors or scalpels during the lumpectomy operation. In addition, as is well understood in the art, wires should be chosen which are of a diameter so as not to cause significant damage to the tissue around the tumor mass. The margin wires can be

made from any well known type of wire which is acceptable for use in medical applications, such as titanium or stainless steel surgical wire. Further, it is contemplated that wires of different shapes can be used. However, it is preferred to use rounded or square wires.

A second embodiment of the invention with deployed wires is shown in Figure 4. In this embodiment, the needle 20 is passed through the tumor mass 80 and the margin wires 10 move back toward the needle 20 in a reverse arc-like manner so as to form a basket 110 around the tumor mass.

In the operation of the second embodiment, after the needle 20 is inserted through the tumor mass 80, the margin wires 10 are moved through the needle 20. The margin wires are passed through a curved channel or segment, for example 92 in Figure 5. The curved segment 92 causes the wire 10 to bend back towards the needle 20 and thereby form a basket or cage 110 around the tumor mass 80. As is shown in Figure 5 and as is well understood in the art, a wire will follow the radius of curvature it last saw i.e., the wire will bend in accordance with the curved portion it most recently was passed through. (For a general discussion, see Doyle, Manufacturing Processes and Materials for Engineers, Prentice Hall, 1961).

As such, different sizes of curves can be used to form various size cages. In addition, the arc length and wire material can be varied to adjust the size of the arc formed by the margin wire. It is also contemplated that other known metal bending techniques can be used to cause the margin wires to follow a predetermined path

after the wires 10 are deployed from the housing needle 20.

It is contemplated that the margin wires 10 can be simultaneously or sequentially deployed. For simultaneous deployment, individual curved channels or segments 92 can be provided for each margin wire 10 to pass through during deployment. For sequential deployment, a single curved channel or segment 92 can be aligned with each margin wire to individually deploy the margin wire 10 in the desired direction.

After all of the wires 10 have been deployed, the wires form a cage or a basket 110 around the tumor mass 80 at a predetermined distance away from the tumor mass 80. The cage or basket 110 is formed from one or more margin wires 10 and can partially or fully surround the tumor mass 80. As discussed above, it is preferred that the margin wires are located approximately 0.7 to 1.3 cm, and most preferably approximately 1 cm, away from the edges of the tumor mass.

It is preferred, for safety reasons, that the margin wires 10 are not removable from the plunger plate 40. In addition, it is preferred that, after deployment, the plunger plate 40 is firmly attached to the hub plate 50 in order to increase the likelihood that the basket 110 will remain as a single intact unit and to reduce the possibility that the wires or other parts of the apparatus will become separated and wander within the tissue after deployment. In order to further secure the hub plate 50 to the plunger plate 40, the margin wires 10 can include proximal nodes or other protrusions 12 which

become fixed within or just beyond the hub plate 50 upon complete deployment of the margin wires.

After the cage 110 is formed around the tumor mass 80, as shown in Figure 6A, the advancing rod 30 can be retracted and the stabilizing post 60 can be detached from the hub plate 50, as shown in Figure 6B. The needle 20 can then be removed from the site of the tumor. The wire cage 110 with the attached hub plate 50 and plunger plate 40, as shown in Figure 6A, remains embedded in the tissue.

If it is necessary to remove the cage 110 for any reason, the needle can be reinserted and the stabilizing post 60 can be reattached to the deployed cage and the cage can be removed without additional surgery.

After the cage 110 has been deployed and the needle portion 20 is removed, the lumpectomy operation is performed by any of the known methods. The wire cage 110 can be localized by any of the known methods including the use of a metal sensing device, by finger palpation, by preoperative visual inspection and/or by radiographic examination. A small incision is then made and the tissue is dissected until the hub plate 50 of the cage 110 or the cage itself is exposed. A suture can be attached to the hub plate 50 to apply tension to the hub plate and stabilize the deployed cage 110 within the tissue. The tissue along the margin wires 10 of the cage 110 is then dissected and the cage is removed along with the tumor mass and a margin of tumor free tissue.

Any well known type of needle or guide with appropriate modifications can be used, however, large

bore needles are preferred and large bore stereotactic needles are especially preferred. The end of the needle can be of any desired shape, including circular or rectangular and can include beveled edges to facilitate entry of the needle into the tissue.

The original placement of the needle can be accomplished using existing three-dimensional stereotactic technology or under routine mammographic guidance. In addition, other standard techniques for localizing tumors can be used for the initial placement of the needle. However, the needle, using currently available stereotactic devices, is preferably placed within the breast by the stereotactic unit's computer-driven robotics. The tip of the needle is positioned approximately 0.7 to 1.3 cm, and preferably approximately 1 cm, from or beyond the radiologically apparent tumor mass. The placement of the needle at this distance and the use of wire with memory characteristics or the deployment of wire through a curved segment will produce a cage which is approximately 0.7 to 1.3 cm away from the tumor at all positions. To assist in placing the needle, the housing needle may have internal directional grooves or guides to facilitate the proper equidistant spacial placement of the margin wires forming the basket.

It is also contemplated that the apparatus of the present invention can be inserted through a biopsy device or in the location of a biopsy device which has been removed from the breast.

Although the present invention has been described in relation to particular embodiments thereof,

many other variations and modifications and other uses will become apparent to those skilled in the art.

CLAIMS

We claim:

1. An apparatus for defining an area around a mass, comprising:

a needle;

at least one margin wire positioned within said needle; and

a deployer for moving said margin wire between a deployed and undeployed position, wherein when said margin wire is in the deployed position, said margin wire forms at least a partial arc having a predetermined curvature.

2. The apparatus, as recited in claim 1, further comprising means for detaching said margin wire from said needle.

3. The apparatus, as recited in claim 1, wherein at least two margin wires are positioned within said needle.

4. The apparatus, as recited in claim 1, wherein at least four margin wires are positioned within said needle.

5. The apparatus, as recited in claim 1, wherein said margin wire is deployed through a curved segment.

6. The apparatus, as recited in claim 1, wherein said margin wire has memory characteristics.

7. The apparatus, as recited in claim 1, wherein said margin wire is substantially straight when in the undeployed position and said margin wire forms an arc when in the deployed position.

8. The apparatus, as recited in claim 1, wherein said arc is approximately 0.7 cm to approximately 1.3 cm away from an edge of a mass.

9. The apparatus, as recited in claim 1, further comprising a plate for anchoring one side of said margin wire.

10. The apparatus, as recited in claim 1, wherein said arc partially encompasses a mass.

11. The apparatus, as recited in claim 1, wherein said mass is a tumor mass.

12. A method of defining an area around a mass, comprising the steps of:

positioning a needle a predetermined distance from a mass; and

deploying a cage from said needle, wherein said cage at least partially encompasses said mass.

13. The method, as recited in claim 12, wherein an inside edge of said cage is a second predetermined distance from said mass.

14. The method, as recited in claim 12, wherein said cage is comprised of at least one margin wire.

15. The method, as recited in claim 12, further comprising means for detaching said cage from said needle.

16. The method, as recited in claim 12, wherein said cage is comprised of at least two margin wires.

17. The method, as recited in claim 12, wherein said cage is comprised of at least four margin wires.

18. The method, as recited in claim 14, wherein said margin wire is deployed through a curved segment.

19. The method, as recited in claim 14, wherein said margin wire has memory characteristics.

20. The method, as recited in claim 13, wherein said second predetermined distance is approximately 0.7 cm to approximately 1.3 cm.

21. The method, as recited in claim 12, wherein said predetermined distance of said needle is approximately 0.7 cm to approximately 1.3 cm.

22. The method, as recited in claim 21, wherein said positioning of said needle at said distance results in a cage which is approximately 0.7 cm to approximately 1.3 cm away from said mass.

23. A method of removing a mass with an approximately uniform predetermined margin of tissue, comprising the steps of:

locating a mass;

marking an area around said mass, wherein said area is a predetermined and approximately uniform distance from said mass and includes said mass; and

surgically removing said area.

24. The method of removing a mass, as recited in claim 23, wherein said step of marking further includes the steps of:

positioning a needle a predetermined distance from said mass;

deploying a cage from said needle to at least partially encompass said mass; and

detaching said cage from said needle.

25. The method of removing a mass, as recited in claim 24, wherein said step of deploying a cage further comprises the step of deploying at least one margin wire in an arc-like path.

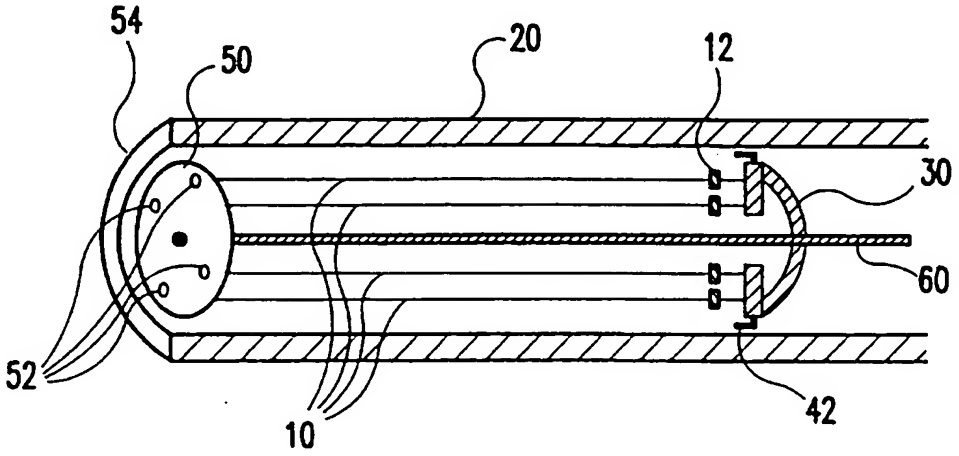

FIG.1

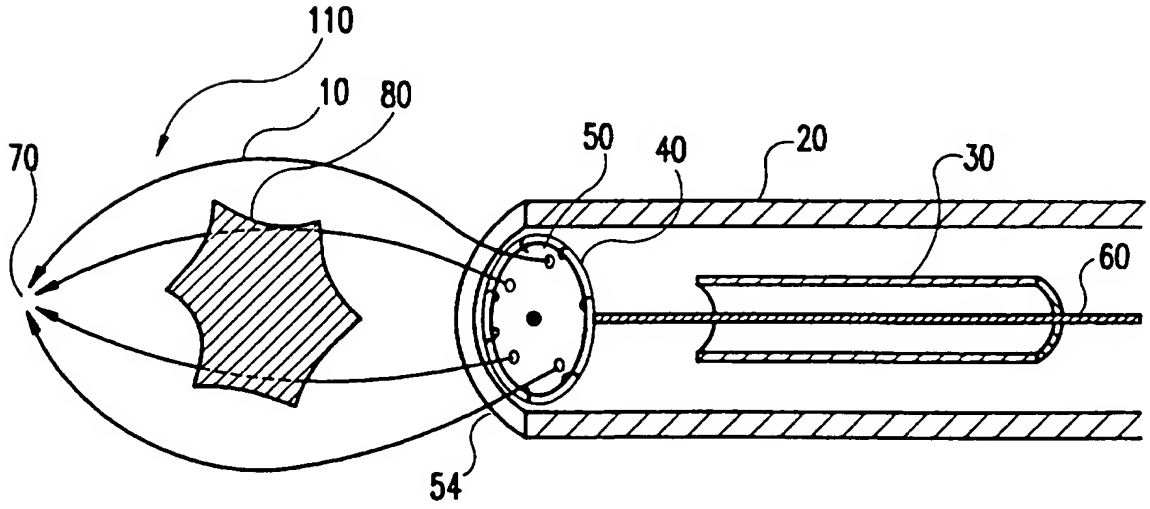

FIG.2

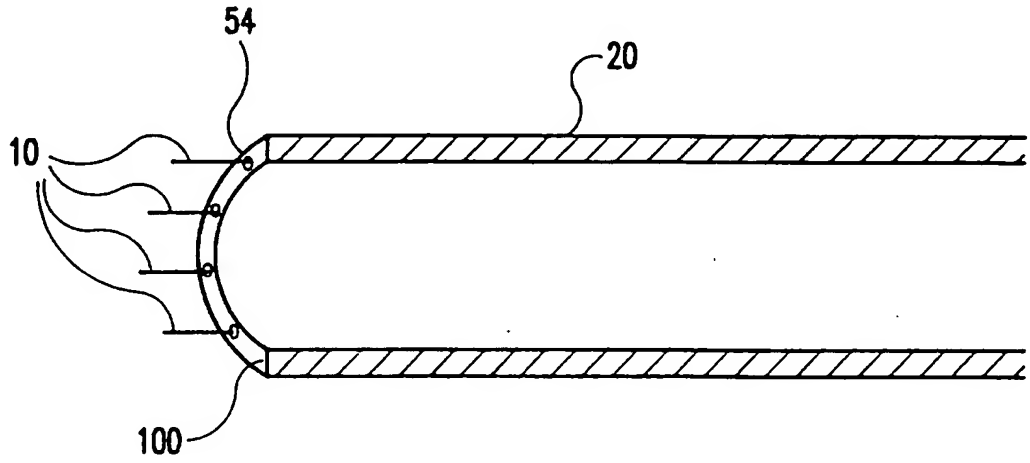

FIG.3

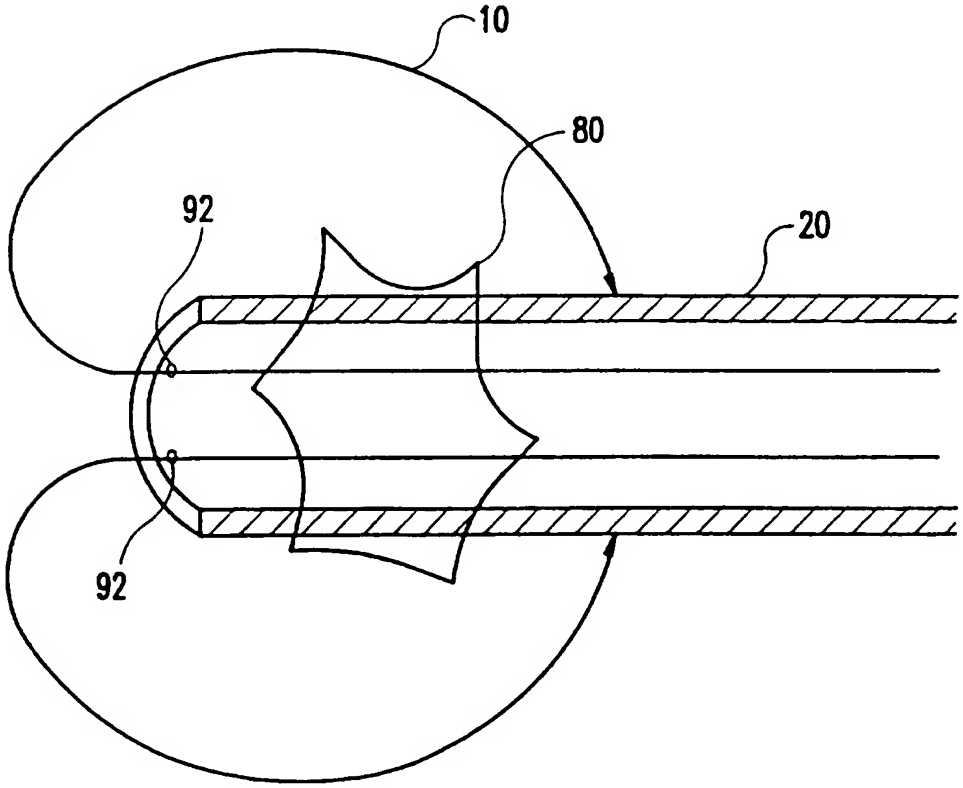

FIG.4

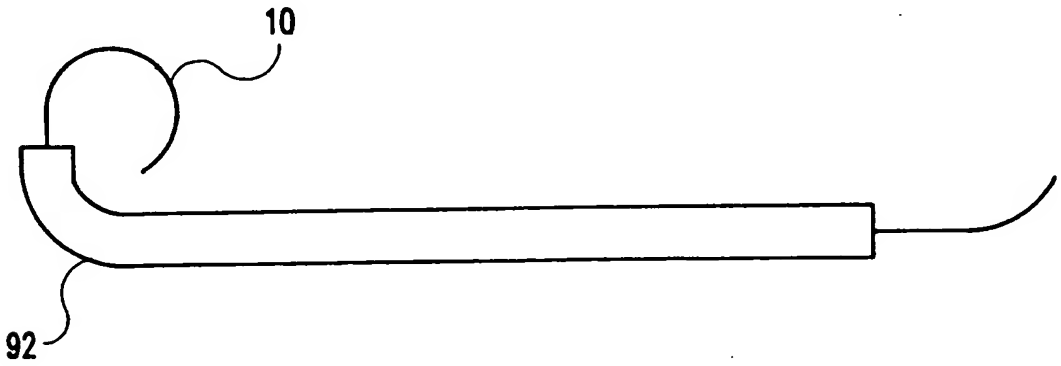

FIG.5

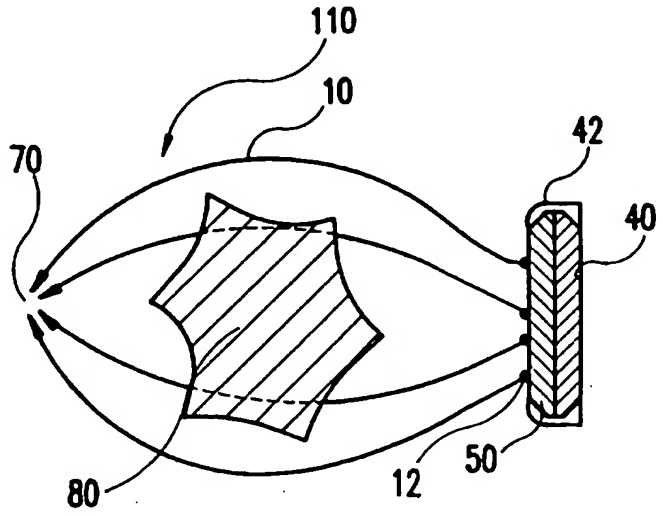

FIG.6A

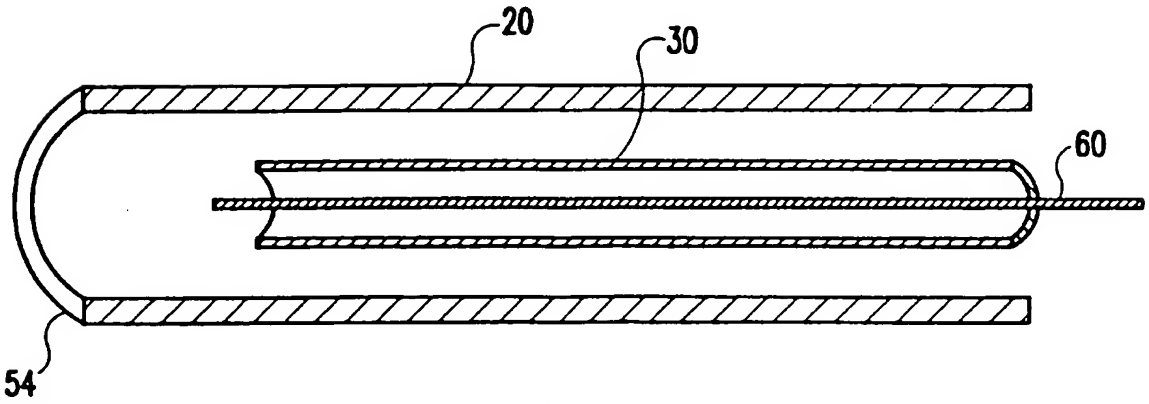

FIG.6B

INTERNATIONAL SEARCH REPORT

Interna[illegible]nal application No.
PCT/US96/15757

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/00; A61D 01/04
US CL :606/116
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/772; 604/164, 264; 606/113, 114, 116, 205, 210

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS
search terms: needle or tube or cannular#, wire#, position? or location?, tumor, and basket or arc.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,083,570 A (MOSBY) 28 January 1992, entire document.	1, 2, 6, 7, 10-15, 19, 23-25. --- 3-5, 8, 9, 16-18, 20-22
Y, P	US 5,496,330 A (BATES et al) 05 March 1996, col. 2, line 38 to col. 6, line 62; and Figs. 2-5.	3-5, 8, 9, 16-18, 20-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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